Drug Discovery, Vol. 11, No. 28, April-June, 2016

COMMUNICATION

ISSN
2278–540X
EISSN
2278–5396

Drug Discovery

An International Journal

FDA Approved Drugs – March 2016

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Publication History
Received: 17 May 2016
Accepted: 28 May 2016
Published: April-June 2016

Citation
Vidhya V. FDA Approved Drugs – March 2016. *Drug Discovery*, 2016, 11(28), 25-28

General Note
Article is recommended to print as digital color version in recycled paper.

TALTZ (IXEKIZUMAB)

Company: Eli Lilly; Approved by March 2016

Specific Treatments: plaque psoriasis

General Information

Taltz (ixekizumab) a humanized interleukin-17A antagonist specifically indicated for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy. It is supplied as an injection for subcutaneous administration. The recommended dose is 160 mg (two 80 mg injections) at Week 0, followed by 80 mg at Weeks 2, 4, 6, 8, 10, and 12, then 80 mg every 4 weeks.

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Mechanism of Action
Taltz (ixekizumab) is a humanized IgG4 monoclonal antibody that selectively binds with the interleukin 17A (IL-17A) cytokine and inhibits its interaction with the IL-17 receptor. IL-17A is a naturally occurring cytokine that is involved in normal inflammatory and immune responses. Ixekizumab inhibits the release of proinflammatory cytokines and chemokines.

Side Effects
Adverse effects associated with the use of Taltz may include: injection site reactions, upper respiratory tract infections, nausea, tinea infections

IDELVION (COAGULATION FACTOR IX (RECOMBINANT), ALBUMIN FUSION PROTEIN)

Company: CSL Behring; Approved by March 2016

Specific Treatments: hemophilia B

General Information
Idelvion is a long-acting albumin fusion protein linking recombinant coagulation factor IX with recombinant albumin. It was specifically approved for use in children and adults with hemophilia B for routine prophylaxis to prevent or reduce the frequency of bleeding episodes; on-demand control and prevention of bleeding episodes; and the perioperative management of bleeding. It is supplied as a powder for solution for intravenous use after reconstitution only.

One IU of Idelvion per kg body weight is expected to increase the circulating activity of Factor IX as follows:

- Adolescents and adults: 1.3 IU/dL per IU/kg
- Pediatrics (<12 years): 1 IU/dL per IU/kg

Administer intravenously. Do not exceed infusion rate of 10 mL per minute.

Mechanism of Action
Idelvion is a recombinant protein that temporarily replaces the missing coagulation Factor IX needed for effective hemostasis. Idelvion is comprised of genetically fused recombinant coagulation Factor IX and recombinant albumin. Fusion with recombinant albumin extends the half-life of Factor IX.

Side Effects
The most common adverse event associated with the use of Indelvion was headache.

KOVALTRY [ANTIHEMOPHILIC FACTOR (RECOMBINANT)]

Company: Bayer; Approved by March 2016

Specific Treatments: hemophillia A

General Information
Kovaltry is a recombinant, human DNA sequence derived, full length Factor VIII concentrate. It temporarily replaces the missing clotting Factor VIII that is needed for effective hemostasis.
Kovaltry is specifically indicated for use in adults and children with hemophilia A (congenital Factor VIII deficiency) for on-demand treatment and control of bleeding episodes, for the perioperative management of bleeding and for routine prophylaxis to reduce the frequency of bleeding episodes.
Kovaltry is supplied as a powder for solution for intravenous use after reconstitution only. The recommended dose is as follows:

Control of bleeding episodes and perioperative management:

- Required dose (IU) = body weight (kg) x desired Factor VIII rise (% of normal or IU/dL) x reciprocal of expected/observed recovery (e.g., 0.5 for a recovery of 2 IU/dL per IU/kg).
- Estimated Increment of Factor VIII (IU/dL or % of normal) = [Total Dose (IU)/body weight (kg)] x 2 (IU/dL per IU/kg).

Routine prophylaxis:

- Adults and adolescents: 20-40 IU/kg 2 or 3 times per week
- Children ≤12 years old: 25-50 IU/kg 2 times per week, 3 times per week or every other day

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Mechanism of Action
Kovaltry is a recombinant, human DNA sequence derived, full length Factor VIII concentrate. It temporarily replaces the missing clotting Factor VIII that is needed for effective hemostasis.

Side Effects
Adverse effects associated with the use of Kovaltry may include: headache, pyrexia, pruritus

DEFITELIO (DEFIBROTIDE SODIUM)

Company: Jazz Pharmaceuticals; Approved by March 2016

Specific Treatments: hepatic veno-occlusive disease with renal or pulmonary dysfunction following HSCT

General Information
Defitelio (defibrotide sodium) is the sodium salt of a mixture of single-stranded oligodeoxyribonucleotides derived from porcine mucosal DNA, which has been shown to have antithrombotic, anti-inflammatory and anti-ischemic properties. It is specifically indicated for the treatment of adult and pediatric patients with hepatic veno-occlusive disease (VOD), also known as sinusoidal obstruction syndrome (SOS), with renal or pulmonary dysfunction following hematopoietic stem-cell transplantation (HSCT). It is supplied as a solution for intravenous infusion. The recommended dose is 6.25 mg/kg every 6 hours given as a 2-hour intravenous infusion. Treat for a minimum of 21 days. If after 21 days signs and symptoms of VOD have not resolved, continue treatment until resolution.

Mechanism of Action
Defitelio (defibrotide sodium) enhances the enzymatic activity of plasmin to hydrolyze fibrin clots *in vitro*. The exact mechanism of action of defibrotide is not fully understood.

Side Effects
Adverse effects associated with the use of Defitelio may include: hypotension, diarrhea, vomiting, nausea, epistaxis

ODEFSEY (EMTRICITABINE, RILPIVIRINE, AND TENOFOVIR ALAFENAMIDE)

Company: Gilead Sciences; Approved by March 2016

Specific Treatments: HIV-1 infection

General Information
Odefsey is specifically indicated as a complete regimen for the treatment of HIV-1 infection in patients 12 years of age and older as initial therapy in those with no antiretroviral treatment history with HIV-1 RNA less than or equal to 100,000 copies per mL; or to replace a stable antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA less than 50 copies per mL) for at least six months with no history of treatment failure and no known substitutions associated with resistance to the individual components of Odefsey. It is supplied as a tablet for oral administration. The recommended dose is one tablet (200 mg of FTC, 25 mg of RPV and 25 mg of TAF) orally once daily with a meal.

Mechanism of Action
Odefsey is a three-drug combination of emtricitabine (FTC) and tenofovir alafenamide (TAF), both HIV nucleoside analog reverse transcriptase inhibitors (NRTIs), and rilpivirine (RPV), a non-nucleoside reverse transcriptase inhibitor (NNRTI).

Side Effects
Adverse effects associated with the use of rilpivirine may include: depressive disorders, insomnia, headache, nausea

ANTHIM (OBILTOXAXIMAB)

Company: Elusys Therapeutics; Approved by March 2016

Specific Treatments: inhalational anthrax

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General Information

Anthim is specifically indicated for use in adult and pediatric patients for the treatment of inhalational anthrax due to *Bacillus anthracis* in combination with appropriate antibacterial drugs and for prophylaxis of inhalational anthrax due to *B. anthracis* when alternative therapies are not available or not appropriate. It is supplied as an injection for intravenous administration. The recommended dose is as follows:

Adults:

- Pre-medicate with diphenhydramine prior to administering Anthim
- Dilute the injection in 0.9% Sodium Chloride Injection, USP, before administering as an intravenous infusion
- Administer a single dose of 16 mg/kg intravenously over 90 minutes (1 hour and 30 minutes)
- See drug label for administration in adult patients weighing less than 40 kg.
- **Pediatrics:**
- Pre-medicate with diphenhydramine prior to administering Anthim
- Dilute the injection in 0.9% Sodium Chloride Injection, USP, before administering as an intravenous infusion
- The recommended dose for pediatric patients is based on weight:
- **Body Weight:** Greater than 40 kg **Dose:** 6 mg/kg
- **Body Weight:** Greater than 15 kg to 40 kg **Dose:** 24 mg/kg
- **Body Weight:** Less than or equal to 15 kg **Dose:** 32 mg/kg
- Administer the recommended dose of Anthim intravenously over 90 minutes (1 hour and 30 minutes)

Mechanism of Action

Anthim (obiltoxaximab) is a monoclonal antibody that binds free PA with an affinity equilibrium dissociation constant (Kd) of 0.33 nM. Obiltoxaximab inhibits the binding of PA to its cellular receptors, preventing the intracellular entry of the anthrax lethal factor and edema factor, the enzymatic toxin components responsible for the pathogenic effects of anthrax toxin.

Side Effects

Adverse effects associated with the use of Anthim may include: headache, pruritus, infections of the upper respiratory tract, cough, vessel puncture site bruise, infusion site swelling, nasal congestion, infusion site pain, urticaria, pain in extremity

CINQAIR (RESLIZUMAB)

Company: Teva Pharmaceuticals; Approved by March 2016

Specific Treatments: severe asthma

General Information

Cinqair is specifically indicated for the add-on maintenance treatment of patients with severe asthma aged 18 years and older with an eosinophilic phenotype. It is supplied as a solution for intravenous administration. The recommended dose is 3 mg/kg once every 4 weeks administered by intravenous infusion over 20-50 minutes.

Mechanism of Action

Cinqair (reslizumab) is an interleukin-5 antagonist monoclonal antibody (IgG4 kappa). IL-5 is the major cytokine responsible for the growth and differentiation, recruitment, activation, and survival of eosinophils. By inhibiting IL-5 signaling, reslizumab reduces the production and survival of eosinophils; however, the mechanism of reslizumab action in asthma has not been definitively established.

Side Effects

Adverse effects associated with the use of Cinqair may include: oropharyngeal pain

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